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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KREMER, MATTHEW J	
ART UNIT	PAPER NUMBER
3736	8

DATE MAILED: 04/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/662,927	SLEPIAN, MARVIN J.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,19-23,27,28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-18,24-26 and 29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The amendments to the specification filed 4/27/2001 have been entered.

Drawings

2. The corrected or substitute drawings were received on 4/27/2001. These drawings are acceptable.

Election/Restrictions

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I is drawn to a system with a sensor for detecting changes in pH, temperature, ion concentration, or analyte concentration.

Group II is drawn to a system with a sensor for detecting stress, strain, shear, flow rate, or pressure.

Group III is drawn to a system with a sensor for detecting a change in placement of the device.

Group IV is drawn to a system with an actuator means with a micromachine that modifies the shape or position of the implant in response to a signal from a sensor.

Group V is drawn to a system with a bioactive, diagnostic, or prophylactic agent or a pH modifying agent.

Group VI is drawn to a system with a sensor for detecting changes in concentration or distribution of cells or tissues or properties of the cells or tissue, changes in metabolic products, changes in antigenicity or cell surface expression, and the presence of foreign depositions including inorganic and microbial materials.

Group VII is drawn to a system with a sensor for detecting changes in weight.

Group VIII is drawn to a system with a sensor for detecting changes in temperature, dimension, vibration, turbulence, pressure, moisture, magnetism, electric potential, electric current, and mechanical or fluid flow properties.

Group IX is drawn to a system with a sensor for measuring tissue fibrosis as changes in stiffness of a tendon, skin stiffness, or muscle tension or rigidity.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 21 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Patrea Pabst on 3/22/2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-9, 19-23, 27-28, and 30-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-18, 24-26, and 29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 provides for the use of the sensor to

measure fouling of the device or sensor over time, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 28 provides for the use of the sensor to measure protein deposition or formation of a bacterial film on a biliary stent, increase in calcification of a urinary stent, or neointimal thickening of an arterial stent, resulting in an increase in thickness, mass, and wall shear, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 27-28 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

9. Claim 3 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 3 states that the data storage means is "within or on the body of the patient" which improperly includes the patient as part of the claimed invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> or
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-9, 19, 21-23, 30, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,399,821 to Bowers. Bowers discloses an implantable animal physiological monitoring system. (Abstract of Bowers). The implantable device

can monitor temperature, heart signals, pressure, and pH and other blood chemistry. (column 3, lines 3-28 of Bowers). The device includes a pulse generator and stimulating electrode to cause the animal to twinge when a physiological parameter falls outside a predetermined range. (column 3, line 62 to column 4, line 58 of Bowers). In regard to claims 2 and 21, the device includes memory contained within the animal. (column 3, lines 52-61 of Bowers). In regard to claims 4-5, 8, 19, 22-23, the device includes a hand-operated unit with display in wireless communication with the implanted sensor. (column 5, lines 2-21 of Bowers). In regard to claim 33, the implantable device includes a microcomputer. (column 6, lines 6-12 of Bowers).

12. Claims 1-9, 19, 21-23 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,248,080 to Miesel et al. Miesel et al. teaches an implantable medical device which telemeters stored data or real-time-sensed data to an external device to derive intracranial gage pressure. (Abstract of Miesel et al.). The medical device includes a temperature or pressure sensor implanted into the brain. The implantable device includes a means of receiving, storing, and transmitting the signals to an external device. The system includes the implantable medical device (IMD) delivering an antibiotic, an antiviral agent, an anti-inflammatory agent, a vaccine, or a drug. (column 6, lines 27-42 of Miesel et al.). In regard to claims 2-3 and 21, the IMD includes RAM. (column 9, lines 1-20 of Miesel et al.). In regard to claims 4-5, telemetry can be employed. (column 8, lines 43-53 of Miesel et al.). In regard to claim 8, the external device is external to the patient. (column 9, line 53 to column 10, line 25 of

Miesel et al.). In regard to claim 9, temperature, pH, or oxygen saturation can be calculated. (column 9, lines 45-52 of Miesel et al.). In regard to claim 23 and 31-32, the system can include transmission of alarms and information via telephone, hardwire, cell phone, satellite, or internet. (column 17,lines 57-65 of Miesel et al.).

13. Claims 1, 4, 8-9, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,201,980 to Darrow et al. Darrow teaches an implantable chemical sensor. The recognition of an analyte is determined by an expandable biochemical sensor that undergoes a dimensional change in the presence of the analyte. (Abstract of Darrow et al.). The monitoring and actuating is being done by the same expandable polymer. The polymer is used in an electronic circuit and when the polymer changes, the electrical properties of the circuit change. The change in electrical properties is detected by an external monitor. (column 3, lines 8-35 of Darrow et al.). In regard to claim 9, glucose is monitored. (Abstract of Darrow et al.).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,399,821 to Bowers as applied to claims 1 and 21, and further in view of 5,411,551 to Winston et al. Bowers does not teach the use of a sensor on a stent. Bowers teaches that other available sensors can be used for sensing blood chemistry. (column 3, lines23-28 of Bowers). It is known in the art that stent devices can be used to sensor blood glucose. (U.S. Patent 5,411,551 to Winston et al. as cited by Applicant). Such a sensor is the type suggested by Bowers. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Bowers to include a sensor for determining blood glucose as disclosed by Winston et al. since Bowers teaches that other sensors for sensing blood chemistry can be used and Winston et al. teaches one such sensor. The combination does not teach a sensor which can measure protein deposition or formation of a bacterial film on a biliary stent, an increase in calcification of a urinary stent, or neointimal thickening of an arterial stent. It is well known in the art that the fouling of a sensor will effect the measurements of that sensor. The discrepancy of the readings would be a measure of the fouling of the sensor on the stent due to protein deposition or formation of a bacterial film on a biliary stent or an increase in calcification of a urinary stent. A measurement of the fouling up of the sensor would indicate that it is time to change the sensor. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include using the discrepancy of the readings to determine that the sensor on the stent is fouled up since it would indicate that it is time to change the sensor.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,312,378 to Bardy teaches an implantable device includes sensors for detecting atrial electrical activity, ventricular electrical activity, time of day, activity level, cardiac output, oxygen saturation, and cardiovascular pressure. (column 5, lines 22-35 of Bardy). The system includes a monitoring means when the received telemetered signals are analyzed and a patient status indicator is generated. (column 6, lines 29-35 of Bardy). The implantable medical device which includes circuitry for recording into a short-term, volatile memory telemetered signals. (column 5, lines 11-21 of Bardy) (claims 2-5 and 21). The monitoring means is in the server system which is outside the patient. (column 6, lines 29-47 of Bardy and Fig. 1) (claim 8). The sensor is connected via telemetry to a programmer (a computer) and sent via the Internet to a server system. (column 5, line 60 to column 6, line 5 of Bardy) (claim 21). U.S. Patent 4,146,029 to Ellinwood, Jr. discloses an implanted housing for dispensing medication with control circuitry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Assistant Examiner
Art Unit 3736
April 2, 2002

ERIC F. WINAKUR
PRIMARY EXAMINER